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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BRET E. FIELD  
BOZICEVIC, FIELD & FRANCIS, LLP  
200 Middlefield Road  
Suite 200  
Menlo Park, CA 94025

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1655

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LD

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/440,829

Applicant(s)

CHENCHIK ET AL.

Examiner

BJ Forman

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-38 is/are pending in the application.
- 4a) Of the above claim(s) 24-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-23 and 35-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Continued Prosecution Application***

1. The request filed on 20 December 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/440,829 is acceptable and a CPA has been established. An action on the CPA follows.

2. This action is in response to papers filed 5 November 2001 in Paper No. 17 in which claims 1 and 36-38 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejection of Claims 36-38 in the Office Action of Paper No. 15 dated 3 August 2001 under 35 U.S.C. 112, second paragraph is maintained. The previous rejections under 35 U.S.C. 103(a) are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Currently claims 1-3 and 7-23 and 35-38 are under prosecution.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 3, 15-17 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 2 and 3 are indefinite in Claim 2 for the recitation "different target nucleic acids are represented in said pattern" because "represented" is a non-specific relational term and therefore the relationship between the target nucleic acids and the pattern are undefined. It is suggested that Claim 2 be amended to define the relationship e.g. replace "are represented in" with "hybridize to oligonucleotide probe spots" (page 21, lines 5-27).

b. Claims 15-17 are indefinite in Claim 15 for the recitation "different target nucleic acids are represented in said pattern" because "represented" is a non-specific relational term and therefore the relationship between the target nucleic acids and the pattern are undefined. It is suggested that Claim 15 be amended to define the relationship e.g. replace "are represented in" with "hybridize to oligonucleotide probe spots" (page 21, lines 5-27)

c. Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: structural elements of the arrays which define or describe "hybridization efficiency"; which define or describe determining "variance in hybridization efficiency"; and which define or describe the structural elements that determine 10-fold variance. It is suggested that the claims be amended to recite the missing structural elements which define or describe "hybridization efficiency", "variance in hybridization efficiency" and "10-fold" "variance".

#### **Response to Arguments**

5. Applicant argues that one of skill in the art would clearly understand the phrase "hybridization efficiency" and how to determine a variance of the efficiency as recited in Claims 36-38. Applicant further argues that in view of the knowledge of one skilled in the art coupled with the working examples within the specification, the claims are clear and not indefinite. The argument is not found persuasive because while the specification provides a general teaching of hybridization efficiency, (page 25, lines 9-27), the specification does not teach a specific structural elements which define or describe hybridization efficiency or variance in hybridization efficiency. Additionally, the claims do not recite structural elements which define or describe efficiency or variance in efficiency whereby one of skill in the art would be appraised of the scope of the claimed invention. Therefore, because the claims do not recite

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the structural elements which define or describe hybridization efficiency and efficiency variance, the claims do not distinctly claim the subject matter which applicant regards as the invention. Hence, the claims are indefinite for omitting essential structural elements.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 7, 8, 10-22 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al. (U.S. Patent No. 5,776,694, issued 7 July 1998).

Regarding Claim 1, Sheiness et al. teach an array (i.e. dipstick) comprising a pattern of probe oligonucleotide spots stably associated with the surface of a solid support (i.e. at least two capture oligonucleotide-coated beads, Column 7, lines 50-61) wherein each probe spot of said pattern comprises a probe composition made up of probes that range in length from about 50 to 100 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28). The courts have stated that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms].") The court stated that "by stating that suitable protection is provided if the protective layer is about 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range." (see MPEP 2144.05 I).

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Additionally, the courts have stated that where the general conditions are known in the art "it is not inventive to discover the optimal or workable ranges by routine experimentation" (*In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probes of about 6 to 150 nucleotides in the array of Sheiness et al. and using routine experimentation derive probes within the range taught by Sheiness et al. (e.g. 50 to 100 nucleotides) to thereby provide the optimal range of nucleotide probe length for the expected benefit of optimizing array components and maximizing array function.

Regarding Claim 2, Sheiness et al. teach the array wherein two or more different target nucleic acids are represented in said pattern i.e. a first bead selectively hybridizes to a prokaryotic nucleic acid target and a second bead selectively hybridizes to a eukaryotic nucleic acid target, Column 7, lines 55-61).

Regarding Claim 3, Sheiness et al. teach the array wherein each probe spot hybridizes to a different target nucleic acid (Column 18, lines 52-56).

Regarding Claim 7, Sheiness et al. teach the array wherein said probes are covalently attached to said surface of said substrate (Column 18 lines 52-55).

Regarding Claim 8, Sheiness et al. teach the array wherein each of said probes is crosslinked to the surface of said support at at least one site i.e. via cyanuric chloride (Column 17, lines 30-65).

Regarding Claim 10, Sheiness et al. teach the array wherein the spots on the array do not exceed a density of about 1000/cm<sup>2</sup> i.e. the preferred bead diameter is .09 inch (0.23 cm) therefore, the beads on the array cannot exceed a density of 1000/cm<sup>2</sup> (Column 16, lines 50-57).

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Regarding Claim 11, Sheiness et al. teach the array wherein the spots on the array do not exceed a density of about  $400/\text{cm}^2$  i.e. the preferred bead diameter is .09 inch (0.23 cm) therefore, the beads on the array cannot exceed a density of  $400/\text{cm}^2$  (Column 16, lines 50-57).

Regarding Claims 12 and 13, Sheiness et al. teach the array comprises from about two to about ten spots (i.e. beads) but they do not teach the number of spot range from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13). However, the courts have stated that when a claimed device recites change in shape, size or dimension of a prior art device, the claimed device is not patentably distinct from the prior art device (531 F.2d at 1053, 189 USPQ at 148; In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed range of spots i.e. from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13) is not patentably distinct from the array of Sheiness et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array comprising 10 spots of Sheiness et al. useful for detecting pathogenic target nucleic acids in a sample (Abstract) and to increase the number of spots to 50 to thereby include 50 known pathogen-specific nucleic acids (Column 43-44) for the expected benefit of providing an array useful for detecting multiple clinically important microbes.

Regarding Claim 14, Sheiness et al. teach an array (i.e. dipstick) comprising a pattern of probe oligonucleotide spots attached the surface of a solid support (i.e. at least two capture oligonucleotide-coated beads, Column 7, lines 50-61) wherein each probe spot of said pattern comprises a probe composition made up of probes that range in length from about 60 to 100 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28) and wherein said probes are covalently bound to said surface of said solid support (Column 18, lines 52-55). The courts have stated that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

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repeated citation unnecessary.

In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range.") (see MPEP 2144.05 I).

Additionally, the courts have stated that where the general conditions are known in the art "it is not inventive to discover the optimal or workable ranges by routine experimentation" (*In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probes of about 6 to 150 nucleotides in the array of Sheiness et al. and using routine experimentation derive probes within the range taught by Sheiness et al. (e.g. 60 to 100 nucleotides) to thereby provide the optimal range of nucleotide probe length for the expected benefit of optimizing array components and maximizing array function.

Regarding Claim 15, Sheiness et al. teach the array wherein ten different target nucleic acids are represented i.e. the dipstick comprises 10 beads and each bead has different capture probes attached (Column 18, lines 46-56).

Regarding Claim 16, Sheiness et al. teach the array wherein each probe spot hybridizes to a different target nucleic acid (Column 18, lines 52-56).

Regarding Claim 17, Sheiness et al. teach the array wherein two probe spots hybridize to the same target i.e. UP553 hybridizes to the complement of UP 053 (Example 8, Column 45, lines 45-55)

Regarding Claim 18, Sheiness et al. teach the array wherein each oligonucleotide ranges from about 65-90 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28) and wherein said probes are covalently bound to said



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surface of said solid support (Column 17, lines 30-34). The courts have stated that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probes of about 6 to 150 nucleotides in the array of Sheiness et al. and using routine experimentation derive probes within the range taught by Sheiness et al. (e.g. 65 to 90 nucleotides) to thereby provide the optimal range of nucleotide probe length for the expected benefit of optimizing array components and maximizing array function.

Regarding Claim 19, Sheiness et al. teach the array wherein the spots on the array do not exceed a density of about 1000/cm<sup>2</sup> i.e. the preferred bead diameter is .09 inch (0.23 cm) therefore, the beads on the array cannot exceed a density of 1000/cm<sup>2</sup> (Column 16, lines 50-57).

Regarding Claim 20, Sheiness et al. teach the array wherein the spots on the array do not exceed a density of about 400/cm<sup>2</sup> i.e. the preferred bead diameter is .09 inch (0.23 cm) therefore, the beads on the array cannot exceed a density of 400/cm<sup>2</sup> (Column 16, lines 50-57).

Regarding Claims 21 and 22, Sheiness et al. teach the array comprises from about two to about ten spots (i.e. beads) but they do not teach the number of spot range from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13). However, the courts have stated that when a claimed device recites change in shape, size or dimension of a prior art device, the claimed device is not patentably distinct from the prior art device (531 F.2d at 1053, 189 USPQ at 148; In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed range of spots i.e. from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13) is not patentably distinct from the array of Sheiness et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array comprising 10 spots of Sheiness et al. useful for detecting pathogenic target nucleic acids in a

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sample (Abstract) and to increase the number of spots to 50 to thereby include 50 known pathogen-specific nucleic acids (Column 43-44) for the expected benefit of providing an array useful for detecting multiple clinically important microbes.

Regarding Claim 35, Sheiness et al. teach a kit comprising the array of Claim 1 (Column 7, lines 48-65).

Regarding Claims 36 and 37, Sheiness et al. teach the arrays of Claims 1 and 14 wherein capture probes are designed and hybridization conditions adjusted using techniques known in the art to provide sensitive and specific detection of targets and optimize simultaneous detection of multiple targets (Column 14, lines 51-65) which clearly suggests the optimized conditions for simultaneous detecting of multiple targets clearly suggests the hybridization efficiency of the probes does not exceed 10-fold. However, the recitation "hybridization efficiency among any two probes...." does not limit the structure of the array because the recitation is functional language.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Therefore, because "hybridization efficiency among any two probes...." does not define the array in terms of structure, the recitation does not further limit the array. Hence, Sheiness et al. teach the array as claimed.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al. (U.S. Patent No. 5,776,694, issued 7 July 1998) in view of Graves, D. (Tibtech, 1999, 17: 127-134).

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Regarding Claim 9, Sheiness et al. teach an array (i.e. dipstick) comprising a pattern of probe oligonucleotide spots stably associated with the surface of a solid support (i.e. at least two capture oligonucleotide-coated beads, Column 7, lines 50-61) wherein each probe spot of said pattern comprises a probe composition made up of probes that range in length from about 50 to 100 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28) wherein said probes are covalently attached to said surface of said substrate (Column 18 lines 52-55) but they do not teach each probe is cross-linked to the surface at at least two sites. However, multiple cross-linked probes were well known in the art at the time the claimed invention was made as taught by Graves. Specifically, Graves teaches that multiple cross-links hold probes firmly in place and improves hybridization signal (page 131, right column, third paragraph, lines 3-8 and page 132, left column, lines 6-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the crosslinking teaching of Graves to the oligonucleotide probe attachment of Sheiness et al. and to crosslink the probes at at least two sites to thereby hold the probes firmly in place for the expected benefit of improving hybridization signal detection as taught by Graves (page 132, left column, lines 6-23).

9. Claims 23 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al. (U.S. Patent No. 5,776,694, issued 7 July 1998) in view of Van Ness et al. (U.S. Patent No. 5,667,976, issued 16 September 1997).

Regarding Claim 23, Sheiness et al. teach an array (i.e. dipstick) comprising a pattern of probe oligonucleotide spots attached the surface of a solid support (i.e. at least two capture oligonucleotide-coated beads, Column 7, lines 50-61) wherein the spots on the array do not exceed a density of about 400/cm<sup>2</sup> i.e. the preferred bead diameter is .09 inch (0.23 cm)

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therefore, the beads on the array cannot exceed a density of  $400/\text{cm}^2$ , wherein said probes are covalently attached to said surface of said substrate (Column 18 lines 52-55) wherein each probe spot of said pattern comprises a probe composition made up of probes that range in length from about 65 to 90 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28) and wherein said probes are covalently bound to said surface of said solid support (Column 17, lines 30-34). Sheiness et al. teach the array wherein the probes are covalently attached to beads and wherein the beads are comprised of any material to which a nucleic acid can be immobilized (Column 16, lines 38-44) but they do not specifically teach the bead is comprised of glass. However, glass beads on arrays (i.e. dipsticks) were well known in the art at the time the claimed invention was made as taught by Van Ness et al. Specifically, Van Ness et al. teach an array (i.e. dipstick) comprising a pattern of probe oligonucleotide spots attached to the surface of a solid support (i.e. two to ten capture oligonucleotide-coated beads, Column 10, lines 24-26) wherein the spots on the array do not exceed a density of about  $400/\text{cm}^2$  i.e. the preferred bead diameter is .09 inch (0.23 cm) therefore, the beads on the array cannot exceed a density of  $400/\text{cm}^2$  (Column 3, lines 53-59) wherein said probes are covalently attached to said surface of said substrate (Column 3 lines 53-59) wherein said probes are covalently bound to said surface of said solid support (Column 10, lines 24-30) and wherein a preferred solid support is glass (Column 4, lines 1-7 and Claim 2). Additionally, Van Ness et al. teach glass beads permit high density oligonucleotide attachment (Column 11, lines 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the glass bead teaching of Van Ness et al. to the solid support of Sheiness et al. who teach any solid support onto which oligonucleotides are attached because Van Ness et al. teach glass is a preferred solid support for high density attachment of nucleic acids (Column 11, lines 54-67). Therefore, one of skill in the art would have been motivated to modify the bead solid support of Sheiness et al. with the preferred glass bead as taught by Van Ness et al. for the expected benefit of high

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density oligonucleotide attachment as taught by Van Ness et al. (Column 11, lines 54-58). Sheiness et al. teach a range of probe length which overlaps the claimed range of 65-90 nucleotides (i.e. the capture oligonucleotides range from about 6 to about 150 bases, Column 14, lines 19-28). The courts have stated that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

*already cited earlier - only 1st time*

In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection is provided if the protective layer is about 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range.") (see MPEP 2144.05 I).

Additionally, the courts have stated that where the general conditions are known in the art "it is not inventive to discover the optimal or workable ranges by routine experimentation" (*In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probes of about 6 to 150 nucleotides in the array of Sheiness et al. and using routine experimentation derive probes within the range taught by Sheiness et al. (e.g. 65 to 90 nucleotides) to thereby provide the optimal range of nucleotide probe length for the expected benefit of optimizing array components and maximizing array function.

Regarding Claim 38, Sheiness et al. teach the array of Claim 23 wherein capture probes are designed and hybridization conditions adjusted using techniques known in the art to provide sensitive and specific detection of targets and optimize simultaneous detection of multiple targets (Column 14, lines 51-65) which clearly suggests the optimized conditions for simultaneous detecting of multiple targets clearly suggests the hybridization efficiency of the probes does not exceed 10-fold. However, the recitation "hybridization efficiency among any

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two probes....” does not limit the structure of the array because the recitation is functional language.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Therefore, because “hybridization efficiency among any two probes....” does not define the array in terms of structure, the recitation does not further limit the array. Hence, *Sheiness et al.* teach the array as claimed.

#### **Response to Declaration**

10. The Declaration filed on 4 June 2001 under 37 CFR 1.132 has been considered but is ineffective to overcome the *Sheiness et al.* reference. The Declaration of Dr. Chenchik is not found persuasive because it merely states that it was expected that “hybridization efficiency would be the same regardless of probe length”. The Declaration does not provide evidence of such expectation. Evidence of such expectation (equal hybridization efficiency) could include a demonstration of the hybridization efficiency for probes longer than 100 or shorter than 50. However, the Declaration does not provide such evidence. Additionally, the Declaration is not found persuasive because the claimed range of probe length overlaps the probe length taught by *Sheiness et al.* The courts have stated that where the general conditions are known in the art “it is not inventive to discover the optimal or workable ranges by routine experimentation” (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235). Therefore, as stated above, the claimed ranges are obvious in view of the teaching of *Sheiness et al.*

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**Conclusion**

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1655  
January 7, 2002